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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/788,110	ZANETTI, MAURIZIO	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *13-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-12 and 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The Amendment filed February 24, 2005 in response to the Office Action of August 25, 2004 is acknowledged and has been entered. Previously pending claims 1-5 have been amended and new claims 19-24 have been added. Upon review and reconsideration, claim 9, 11-12 are hereby rejoined to the claimed invention Claims 1-12 and 19-24 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. It is noted that Applicant states that the inclusion of claim 59 in the previous action was a clerical oversight, given that claim 59 is not recited in the current claim set. Examiner's appreciates Applicant's careful review of the case and confirms that the recitation of claim 59 in the previous action was indeed an inadvertent typographical error and that it is clear from the action as a whole (wherein claims 1-8 and 10 are shown to be under prosecution in Section 1, shown to be elected in Section 2, are rejected in Section 8), and in particular in the rejection under 35 USC 102 (wherein Examiner specifically draws attention to adjuvants in the prior art reference) that the claim recited as claim 59 was intended to be claim 10. Examiner apologizes for any inconvenience and therefore makes this action non-final.

4. It has come to Examiner's attention that the amendments to the specification submitted in the Preliminary Amendment submitted November 18, 2003 have not been entered. The page numbers listed in the amendment do not correspond to the page numbers of the originally submitted application. For example, Applicant asks for the replacement of the paragraph beginning on line 4 on page 14 with a paragraph drawn to hTRT synthetic peptides. However, a review of page 14 reveals that no new paragraph beings on line 4 of page 14. A further review

reveals that a new paragraph dealing with hTRT synthetic peptides begins on line 21 of page 12. Although Applicant's attempt to remedy sequence identifier errors in the specification was clearly bona fide, Applicant must submit an amendment drawn to the specification as originally filed in order to comply with the sequence rules.

5. The following rejections are being maintained:

Maintained and New Claim Rejections - 35 USC 112

6. Claims 1-8 and 10 remain rejected under 35 USC 112, first paragraph, claims 9, 11-12 are rejected under 35 USC 112, first paragraph, and newly added claims 19-24 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in the Paper mailed August 25, 2004, Section 7, pages 3-10.

Applicant cites *In re Marzocchi*, "it is incumbent upon the Patent Office.....to explain why it doubts the truth or accuracy of any statement in supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning" and argues that in view of In *re Marzocchi*, Examiner fails to provide adequate explanation, evidence or reasoning as to why the Applicant's specification fails to enable the scope of the invention as claimed. The argument has been considered but has not been found persuasive given the lengthy rejection which encompasses both sound scientific reasons and objective evidence specifically drawn from those of skill in the art which clearly reveals why Examiner doubts the truth or accuracy of statements in supporting disclosure.

Applicant further states that instead of providing adequate explanation, evidence or reasoning as to why the Applicant's specification fails to enable the scope of the invention as claimed, Examiner summarily applies an "undue experimentation' stamp on the case to improperly advance a *prima facie* case.

Given the reasons set forth previously and above, it is clear that the only reasonable conclusion available to Examiner is to find that undue experimentation would be required to practice the claimed invention. This finding is clearly based on the lengthy rejection which encompasses both sound scientific reasons and objective evidence specifically drawn from those of skill in the art which clearly reveals why Examiner doubts the truth or accuracy of statements in supporting disclosure.

Applicant further traverses the finding of undue experimentation and cites *Ex parte Jackson* "a considerable amount of experimentation is permissible...if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed", as well as other court cases drawn to the same issue. Applicant argues that Examiner's case needs to be based on evaluation of Applicant's teaching and is not satisfied by the Examiner's personal speculation about hypothetical "problems" associated with vaccine development or citation to alleged technical problems encountered by others in published references.

The argument has been considered but has not been found persuasive because it is clear that Examiner carefully reviewed and evaluated the teachings of the specification, in particular, Examiner suggests that Applicant review the summary of the claimed invention on pages 3-5 of the prior action wherein Examiner carefully reviewed the teachings of the specification. These teachings were then evaluated based on sound scientific reasoning and the teachings of those of skill in this particular art. Contrary to Applicant's arguments, the recitation of "problems" associated with vaccine development are not personal speculation about hypothetical problems, but rather the result of findings of those skilled in the

art. Further, it is unclear why Applicant considers that the technical problems in the peer reviewed published references are merely "alleged".

Applicant argues that Examiner's observations that "it cannot be predicted from the information in the specification as to whether or not the claimed vaccine is either safe or possible to use as contemplated." and that "one cannot extrapolate the teaching of the specification to the enablement of the claims because neither the *in vitro* nor the *in vivo* studies presented in the specification are commensurate in scope with the claimed invention which is drawn to a universal vaccine for the treatment of cancer." are of no moment given the rejection based on Examiner's personal speculations, hypothetical problems and citation of alleged technical problems.

The argument has been considered but has not been found persuasive for the reasons set forth above. Further, simply to clarify the record, although the issue of safety is not an issue addressed by the PTO, Examiner's statement was made only in response to the teaching of the specification wherein Applicant specifically states that "further experimentation is needed to determine whether hTRT-based vaccination in cancer patients is safe or possible (para bridging pages 29-30)." Since Applicant apparently did not know, at the time the application was filed if the claimed invention was safe or even possible, Applicant himself calls into question the usefulness of the claimed invention, Thus it is appropriate for Examiner to reiterate said question when discussing the enablement of the claimed invention. Applicant's arguments have not been found persuasive and the rejection is maintained.

Finally, as drawn to newly added claims 19-24, although the claims 21 and 22 are specifically drawn to SEQ ID NO:1 and SEQ ID NO:2, and claim 20 is

specifically drawn to HLA-2A.1, the claims are not enabled for the reasons set forth previously and above. In particular, although the specification discusses the activity of precursor cancer patient T cells stimulated with SEQ ID NO:1 or SEQ ID NO:2 *in vitro*, and demonstrates generation of SEQ ID NO:1 and 2 specific CTL response in HLA-A2.1 transgenic mice there is no teaching or suggestion that either SEQ ID NO:1 or SEQ ID NO:2 is effective for treatment of any tumor *in vivo*. For the reasons set forth previously and above, in the absence of objective evidence demonstrating that the claimed invention is effective in a mammal with a tumor load, no one of ordinary skill would believe it more likely than not that the invention would function as claimed with a reasonable expectation of success.

7. Claims 1-8 and 10 remain rejected under 35 USC 112, first paragraph for the reasons drawn to HLA expression, calls 9 and 11-12 are rejected under 35 USC 112, first paragraph and newly added claims 19, 21-24 are rejected under 35 USC 112, first paragraph for the reasons drawn to HLA expression previously set forth in the Paper mailed August 25, 2004, Section 8, pages 10-11 as well as for the reasons set forth above.

Applicant argues that Examiner admits on the record that the specification is enabling for a universal vaccine for treating tumors of any origin comprising SEQ ID NO:1 and 2 wherein the patients treated express HLA-A2.1 and cites *In re Fisher* "[a]s long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim then the enablement requirement of 35 USC 112 is satisfied". Applicant further argues that Examiner's admission is the best rebuttal to the pending rejection under 35 USC 112, first paragraph. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the

claims as currently constituted. Further, Applicant is misrepresenting Examiner's statement which in full reads "If Applicant were able to overcome the rejection set forth above claims 1-8" .....would still be rejected because. Given the rejection set forth above and previously it is clear that the specification does not disclose at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim and *In re Fisher* does not apply. Upon overcoming the prior 112, first paragraph rejection set forth in Section 7 of the previous action and amending the claims to the scope that Examiner stated was enabled in Section 8, the claims would indeed appear to be allowable. However, since Applicant has not overcome the rejection for the reasons set forth above, has not amended the claims, Examiner finds that the instant invention is not enabled.

Applicant further argues that Applicant's presentation of both a functional assay and structural motif provide a teaching sufficient to allow for the synthesis of any TRT peptide that is capable of initiating and/or enhancing a CTL response restricted by a given MHC receptor. The argument has been considered but has not been found persuasive for the reasons set forth previously. Further, as drawn to the structural motif, Applicant is arguing limitations not recited in the claims as currently constituted.

Applicant amends claim 1 to delete the term "universal". Applicant argues that deletion of the term changes the scope of the pending claims and thus the pending claims are now enabled. The argument has been considered but has not been found persuasive, the claims as currently constituted read on treating any cancer with any TRT peptide. The deletion of the term "universal" does not in fact alter the scope of the claims. Further although the newly added claims are drawn to HLA-A2 restricted telomerase reverse transcriptase peptides, the claims are not

enabled because the Applicant has not overcome the rejections set forth in Section 7 of the previous office action and even if the Applicant had overcome the rejection set forth in Section 7 the claims would not be enabled for the reasons set forth previously and below.

Maintained and New Claim Rejections - 35 USC 102

8. Claims 1, 6, 8, 10 remain rejected under 35 USC 102(b) and newly added claims 19-24 are rejected under 35 USC 102(b) for the reasons previously set forth in the Paper mailed August 25, 2004, Section 10, page 12 and further for the reasons set down below.

Given that the specification does not define the term "peptide", it is noted that Taber's Cyclopedic Medical Dictionary (16th Ed, F.A. Davis Company, Philadelphia, 1989, p. 1355 defines a peptide as "a compound ....containing two or more amino acids".

Applicant argues that US Patent No. 6,093,809 is silent on a vaccine for treating tumors of any origin, initiating and enhancing a cytotoxic CTL response, a helper peptide and fails to disclose each and every element of the selected embodiments of the invention as presently claimed. Further, newly added claims 19-24 are drawn to the limitation of "composition .....comprising at least one HLA-A2-restricted telomerase reverse transcriptase (TRT) peptide.

The argument has been considered but has not been found persuasive because for the reasons set forth below and further because Examiner clearly stated that "It is noted that the preamble recitation of a universal vaccine is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is a human telomerase reverse transcriptase peptide and a physiologically acceptable

carrier, an adjuvant." It is clear that the limitation of the claim "in an amount effective for initiating and enhancing a cytotoxic T lymphocyte response" is drawn to the activity of the vaccine and that this vaccine activity is merely suggestive of an intended use and for the reasons set forth previously is not given weight for purposes of comparing the claims with the prior art. Specifically and again, the claims read on the active ingredients per se which are a human telomerase reverse transcriptase peptide and an adjuvant. Since claim 1 has been amended to recite "and a helper peptide" and claim 24 recites a helper peptide, the compositions of claim 1 and claims dependent on claim 1 as well as claim 24 are now drawn to the previously recited ingredients as well as a "helper peptide. However, in regard to Applicant's argument that US Patent No. 6,093,809 does not teach a helper peptide, this is in fact not the case. A review of column 30 reveals that the adjuvants cited previously include keyhole limpet hemocyanin which is a well known carrier protein, having more than two amino acids, which is a helper peptide.

Thus, the rejection is hereby reiterated and added to as set forth below:

It is noted that the recitations of a vaccine, the recitation of a composition for the induction of a cytotoxic T lymphocyte response, the limitation of effective for initiating and enhancing a cytotoxic T lypmphocyte response are merely suggestive of an intended use and are not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which are a human telomerase reverse transcriptase peptide, a physiologically acceptable carrier, a helper peptide.

The claims are drawn to a vaccine comprising at least one telomerase reverse transcriptase peptide and a helper peptide (claim 1), wherein said peptide is a human peptide (claim 6), wherein said peptide is effective alone (claim 8),

wherein said vaccine comprises ad adjuvant (claim 10) a composition comprising at least one HLA-A2-restricted telomerase transcriptase peptide and a physiologically acceptable carrier (claim 19), wherein said HLA-A2 is HLA-A2.1 (claim 20), wherein said at least one TRT peptide comprises a peptide with a sequence set forth as SEQ ID NO:1 (claim 21), comprises a peptide with a sequence set forth as SEQ ID NO:2 (claim 22), comprises a peptide with a sequence set forth as SEQ ID NO:1 and SEQ ID NO:2 (claim 23) wherein the composition further comprises a helper peptide (claim 24).

US Patent No. 6,093,809 teaches human telomerase reverse transcriptase (see abstract) and specifically teaches the production of antibodies to said human telomerase reverse transcriptase comprising immunizing various hosts by injection of the telomerase protein in combination with various adjuvants including keyhole limpet hemocyanin which is a well known carrier protein, having more than two amino acids, which is a helper peptide (col 30, lines 19-31). Further, a review of the '809 specification reveals a telomerase peptide useful for the method taught wherein said peptide comprises SEQ ID NO:1 (see SEQ ID Nos: 217 and 225 of the '809 patent) and reveals a telomerase peptide useful for the method taught wherein said peptide comprises SEQ ID NO:2 (see SEQ ID Nos:217 and 225 of the '809 patent), and thus the reference teaches a telomerase peptide comprising both SEQ ID NO:1 and SEQ ID NO:2. Finally, although the prior art patent does not teach that the peptide comprises at least one HLA-A2-restricted peptide/HLA-A2.1, given that the sequences of the prior art peptide comprise SEQ ID NO:1, SEQ ID NO:2, it appears that the invention of the prior art and the instant invention are in fact the same. The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art

does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the homoconjugates are functionally different than those taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

New Claim Rejections

Claim Rejections - 35 USC 112

9. Claims 1-12 and 24 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a "helper peptide" in the absence of the modifier, SEQ ID NO:4 has no clear support in the specification and the claims as originally filed. Applicant points to published paragraphs 0054, 0074 and Table II for support for the newly added limitation. A review of the specification reveals support for "helper peptide on page 14, as follows:

> "In vivo immunization 10 HHD mice were immunized subcutaneously at the base of the tail with 100 g of individual hTRT peptide emulsified in incomplete Freumds' adjuvant (IFA). Half of the mice were immunized with the hTRT peptide and 140 pg of the helper peptide TPPAYRPPNAPV, which corresponds to residues 128-140 of the hepatitis B core antigen (HBVc)",

On page 21, as follows:

> "Both p540 and p865 were able to induce specific CTL responses (Table 11) although differences were noted. ln fact, p540 induced CTL whether alone or in combination with a helper peptide (66 vs. 80 % responders)",

It is noted that in Table II, helper peptide TPPAYRPPNAPV, SEQ ID NO:4, is specifically identified. The suggested support has been considered but is not

persuasive because the only disclosure of helper peptide in the specification is helper peptide in conjunction with SEQ ID NO:4, TPPAYRPPNAPV. The specification does not contemplate, make any suggestion of or provide guidance on the broadly claimed helper peptide. The subject matter claimed in claims 1-8, 10 and 24 broadens the scope of the invention as originally disclosed in the specification.

10. Claims 21-23 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a peptide comprising SEQ ID NO:1, comprising SEQ ID NO:2 has no clear support in the specification and the claims as originally filed. Applicant points to Example 11 and Tables II and II for support for the newly added limitation. A review of Example 11 reveals support for peptides consisting of SEQ ID NO:1 and SEQ ID NO:2. A review of Table II reveals support for peptides consisting of SEQ ID NO:1 and SEQ 2. A review of Table III reveals support for peptides consisting of SEQ ID NO:1 and SEQ ID NO:2. However, no support was found in the specification or claims as originally filed for compositions which comprise TRT peptides wherein said peptides comprise SEQ ID NO:1 or SEQ ID NO:2. The subject matter claimed in claims 21-23 broadens the scope of the invention as originally disclosed in the specification.

11. Claims 23 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a composition comprising "a first peptide.....and a second peptide....." has no clear support in the specification and the claims as originally filed. Applicant points to Example 11 and Tables II and II for support for the newly added limitation. A review of Example 11 reveals support for peptides consisting of SEQ

ID NO:1 and SEQ ID NO:2. A review of Table II reveals support for peptides consisting of SEQ ID NO:1 and SEQ 2. A review of Table III reveals support for peptides consisting of SEQ ID NO:1 and SEQ ID NO:2. However, no support was found in the specification or claims as originally filed for compositions which comprise both SEQ ID NO:1 and SEQ ID NO:2. The subject matter claimed in claim 23 broadens the scope of the invention as originally disclosed in the specification.

12. Claims 1-5, 8-12, 19, 20, 24 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims 1-5, 8-12, 19, 20, 24 are drawn to a telomerase reverse transcriptase (TRT) peptide. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function,

> as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The invention at issue in Lilly was a DNA construct per se, the holdings of this case is also applicable to claims such as those at issue here, that is claims drawn to telomerase reverse transcriptase (TRT) peptides.

Thus, the instant specification may provide an adequate written description of a telomerase reverse transcriptase (TRT) peptide, per Lilly by structurally describing a representative number of a telomerase reverse transcriptase (TRT) peptide or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

In this case, the specification does not describe a telomerase reverse transcriptase (TRT) peptide required to practice the method of the pending claims in a manner that satisfies the Lilly standards since it only describes a single human telomerase reverse transcriptase peptide and isolated fragments thereof. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to

the members of the genus, which features constitute a substantial portion of the genus. Athough the claims state that the peptide is effective for initiating/enhancing a CTL response against mammalian cancer cells, a definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is and neither the specification nor the claims describe a TRT peptide required to practice the claimed invention in a manner that satisfies Lilly.

Thus, the specification does not provide an adequate written description of the broadly claimed telomerase reverse transcriptase peptide and or isolated fragments thereof that is required to practice the claimed invention.

14. Claims 21-23 are drawn to peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the

> art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The invention at issue in Lilly was a DNA construct per se, the holdings of this case is also applicable to claims such as those at issue here, that is claims drawn to peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2.

Thus, the instant specification may provide an adequate written description of peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2, per Lilly by structurally describing a representative number of peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2 or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

In this case, the specification does not describe peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2 required to practice the method of the pending claims in a manner that satisfies the Lilly standards since it only describes a single human telomerase reverse transcriptase and isolated fragments thereof.

Therefore, it necessarily fails to describe a "representative number" of species comprising the claimed sequences. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Although the claims state that the peptide is effective for initiating/enhancing a CTL response against mammalian cancer cells, a definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is and neither the specification nor the claims describe a TRT peptide required to practice the claimed invention in a manner that satisfies Lilly.

Thus, the specification does not provide an adequate written description of the broadly claimed peptides comprising SEQ ID NO:1, SEQ ID NO:2, SEQ ID Nos 1 and 2 that is required to practice the claimed invention.

15. Claim 8 is rejected under 35 USC 112, second paragraph because claim 8 recites the limitation "wherein the peptide is effective alone". Since claim 1 is drawn to both a TRT peptide and a helper peptide, it is not possible to determine to which peptide claim 8 refers and the metes and bounds of the claim cannot be established.

Claim Rejections - 35 USC 102

16. Claims 1, 6-12, 19-24 are rejected under 35 USC 102(e) as being anticipated by WO 00/25813.

It is noted that the preamble recitation of a vaccine is merely suggestive of an intended use and is not given weight for purposes of comparing the claims with the prior art. The claims read on the active ingredients *per se*, which is a human telomerase reverse transcriptase peptide, SEQ ID NO:1, SEQ ID NO:2, a physiologically acceptable carrier, an adjuvant, a helper peptide.

The claims are drawn to a vaccine comprising at least one telomerase reverse transcriptase peptide and a helper peptide (claim 1), wherein said peptide is a human peptide (claim 6), wherein said peptide is from about 7 to 15 amino acid residues in length (claim 7) wherein said peptide is effective alone (claim 8), in combination with other peptides (claim 9), wherein said vaccine comprises ad adjuvant (claim 10), wherein the carrier is a mammalian cell (claim 11), wherein the carrier mammalian cell is a transfected or transgenic cell (claim 12), a composition comprising at least one HLA-A2-restricted telomerase transcriptase peptide and a physiologically acceptable carrier (claim 19), wherein said HLA-A2 is HLA-A2.1 (claim 20), wherein said at least one TRT peptide comprises a peptide with a sequence set forth as SEQ ID NO:1 (claim 21), comprises a peptide with a sequence set forth as SEQ ID NO:2 (claim 22), comprises a peptide with a sequence set forth as SEQ ID NO:1 and a sequence set forth as SEQ ID NO:2 (claim 23) wherein the composition further comprises a helper peptide (claim 24).

WO 00/25813 teaches a vaccine comprising at least one human telomerase reverse transcriptase peptide, SEQ ID NO:1, identical to the instantly claimed SEQ ID NO:1 as well as vaccines with/including other hTERT peptides (p. 4, lines 1-5), including SEQ ID NO:4 which is 100% identical to the instantly claimed SEQ ID NO:2 wherein both peptides are nine amino acid residues in length, wherein they are HLA-A2.1 restricted peptides since they are identical to the currently claimed peptides, wherein the vaccine comprises an adjuvant, comprises more than one hTERT peptide (p. 11, lines 6-12) wherein pharmaceutically acceptable carriers are well known in the art (p. 13, lines 7-14) and wherein a carrier is KLH, a helper peptide (p. 8, lines 7-15), wherein the carrier is an antigen presenting cell (p. 10, lines 7-11, p. 11, lines 4-12), wherein the peptides are transformed or transfected

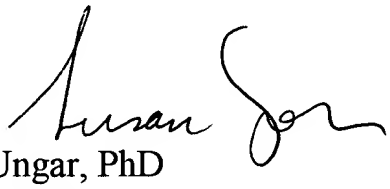
into cells wherein a nucleic acid that encodes a polypeptide of the invention is introduced by means of recombinant DNA techniques (p. 15, lines 14-19) and specifically teaches methods of transfecting APC in order to display the peptides of the invention on the surface of the APC (pages 49-50) wherein adjuvants include but are not limited to cytokines which are helper peptides (p. 90). All of the limitations of the claims are met.

16. All other rejections and objections set forth in the Office Action mailed August 25, 2004 are hereby withdrawn.

17. No claims allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at 571-272-0787. The fax phone number for this Art Unit is (571) 273-8300.



Susan Ungar, PhD
Primary Patent Examiner
May 3, 2005